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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/522,351      | 01/26/2005  | Bruce J. Simon       | 5490E-292/NPB       | 6317             |

7590 03/30/2007  
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| EXAMINER |
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FERNANDEZ, SUSAN EMILY

|          |              |
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| ART UNIT | PAPER NUMBER |
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1651

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 31 DAYS                                | 03/30/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/522,351

Applicant(s)

SIMON, BRUCE J.

Examiner

Susan E. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

### **DETAILED ACTION**

Claims 1-14 are pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5 and 9-14, drawn to a method and a composition for treating a tissue defect in a human or other animal subject.

Group II, claim(s) 6-8, drawn to a method of enhancing cell proliferation in a tissue culture of interest.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A “special technical feature” is defined by PCT Rule 13.2 as “those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” In the instant case, as discussed below, certain embodiments of claimed inventions fail to make any contribution over the prior art. Because certain embodiments of the claimed inventions fail to make any contribution over the prior art, the claims as filed fail to contain a single common special technical feature supporting a showing unity of invention.

Specifically, as evidenced by the International Search Report, which is part of the record in this application, it is clear that at least two publications, Kipshidze et al. (Lasers in Surgery

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and Medicine. 2001. 28: 355-364) and Nicolson et al. (Clin. Expl. Metastasis. 1991. 9(5): 457-468), demonstrate that the claims presented for examination at the very least lack an inventive step. Because the claims as filed lack a common special technical feature which defines them over the prior art, the claims lack unity.

Lack of a common special technical feature, and therefore lack of unity, is further demonstrated by the fact that Group I requires that an extracted medium is administered to the site of a tissue defect in a human or other animal subject, not recited in Group II. Thus, a reference which anticipates Group I, for example, would not necessarily anticipate Group II. See also Kipshidze et al. and Nicolson et al. listed on the International Search Report, which anticipate Group II but do not anticipate Group I. It is clear that each of the inventions recited in the two groups lacks a technical feature in common.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (a) the carriers recited in claim 12;
- (b) the growth active materials recited in claim 14.

Applicant is required, in reply to this action, to elect a single species, **from each of (a) and (b) above**, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any

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claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Moreover, should applicant elect "an osteoconductive carrier" for (a), applicant is further required to elect an osteoconductive carrier recited in claim 13.

Thus, a proper election would appear as follows: --

Applicant hereby elects Group I, claims 1-5 and 9-14, with traverse. For the species election, applicant elects, also with traverse, an osteoconductive carrier for species (a), bone particles as the osteoconductive carrier, and growth factors for species (b).

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 12-14

The following claim(s) are generic: 1-11.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the compounds recited have different structures and properties, and are derived from different materials. Moreover, the compounds recited would have treated different tissue defects.

Though there is no burden requirement for lack of unity, it should be noted that because these inventions are independent or distinct for the reasons given above and there would be a

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serious burden on the examiner if restriction is not required because the inventions require a different field of search, restriction for examination purposes as indicated is proper.

**Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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